PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Commissioner
US Department of Commerce
United States Patent and Trademark Office, PCT
2011 South Clark Place Room
CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 30 October 2000 (30.10.00)	
International application No. PCT/IE00/00033	**Applicant's or agent's file reference** P7965.WO
International filing date (day/month/year) 20 March 2000 (20.03.00)	**Priority date** (day/month/year) 18 March 1999 (18.03.99)
Applicant CALDWELL, Martin et al	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

11 September 2000 (11.09.00)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Zakaria EL KHODARY
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
P7965.WO		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/IE00/00033	20/03/2000	18/03/1999
International Patent Classification (IPC) or national classification and IPC A61B17/34		
Applicant GAYA LIMITED et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 6 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
11/09/2000	26.07.2001
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized officer Moers, R Telephone No. +31 70 340 2375

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IE00/00033

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:
Description, pages:

4-7	as originally filed			
1,1a,2,3	as received on	25/04/2001	with letter of	23/04/2001

Claims, No.:

1-10	as received on	25/04/2001	with letter of	23/04/2001

Drawings, sheets:

1/4-4/4	as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   - ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
   - ☐ the language of publication of the international application (under Rule 48.3(b)).
   - ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   - ☐ contained in the international application in written form.
   - ☐ filed together with the international application in computer readable form.
   - ☐ furnished subsequently to this Authority in written form.
   - ☐ furnished subsequently to this Authority in computer readable form.
   - ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   - ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-10
	No:	Claims	
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-10
Industrial applicability (IA)	Yes:	Claims	1-10
	No:	Claims	

2. Citations and explanations
   see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

1. Document **US 5514133 A** (**D1**) discloses (see Figs. 1 and 3):
A surgical access device 22 having:
body cavity engagement means 14 for insertion into the incision;
fixing means 12 for attaching the device to a patients skin;
a sleeve 16 connected between the body cavity engagement means 14 and the fixing means 12 defining an access port, whereby
the fixing means 12 is a proximal (flat) ring;
the sleeve 16 is adjustable by the positioning of the proximal ring (if the lower ring is pulled against the inside of the abdominal wall, the sleeve can be adjusted by "positioning" the proximal ring downwards);
the positioning of the proximal ring 12 contracting the sleeve and creating a seal between the incision and the sleeve;
the proximal ring 12 having an associated connector ring 40 suitable to receive additional seals or medical instruments; and
sealing means 56 operating on the sleeve to prevent leakage of gas.

Thus D1 discloses all the features of independent claim 1, except for the fact that the sleeve is contracted instead of retracted when the proximal ring is "positioned".

It would only be an obvious modification to provide the device of D1 with an alternative adjustable sleeve such as in **US-A-5524644** (**D3**) which discloses a sleeve that is retracted by rolling of a proximal ring. The skilled person would incorporate this feature in the device of D1 without using any inventive skill.

2. Dependent claims 2-10 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step, the reasons being as follows:
- claim 2: see D1;
- claims 3, 4, 6 and 10: providing the device of D1 with an alternative valve at the distal side would be an obvious modification for the skilled person, as is apparently also recognised by the applicant, see description, page 7, lines 5 and 6. Such an alternative valve is known from **WO 9522289 A** (**D2**), see Fig. 15;
- claim 5: foam is a material that is well known in the art for use as valve material;
- claim 7: see D1;
- claim 8: see D3, col. 3, line 18; and

- claim 9: see D1.

Re Item VIII

Certain observations on the international application

1. The term "connectable" in line 12 of claim 1 is not clear.

2. It is not clear in lines 17 and 19 of claim 1 how the "positioning of the proximal ring" would adjust the sleeve.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
P7965.WO		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/IE 00/00033	20/03/2000	18/03/1999
Applicant		
GAYA LIMITED et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 3 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the **language,** the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   [ ] the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

   b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

   [ ] contained in the international application in written form.

   [ ] filed together with the international application in computer readable form.

   [ ] furnished subsequently to this Authority in written form.

   [ ] furnished subsequently to this Authority in computer readble form.

   [ ] the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   [ ] the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. [ ] **Certain claims were found unsearchable** (See Box I).

3. [ ] **Unity of invention is lacking** (see Box II).

4. With regard to the **title,**

   [ ] the text is approved as submitted by the applicant.

   [X] the text has been established by this Authority to read as follows:

   A SURGICAL ACCESS DEVICE

5. With regard to the **abstract,**

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. 2

   [ ] as suggested by the applicant.

   [ ] because the applicant failed to suggest a figure.

   [X] because this figure better characterizes the invention.

   [ ] None of the figures.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IE 00/00033

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/34

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 5 514 133 A (STEIN H DAVID ET AL) 7 May 1996 (1996-05-07) column 3, line 61 -column 5, line 14; figures 1-5	1,2,7-9 3-6
Y	WO 95 22289 A (BONADIO FRANK ;GAYA LTD (IE)) 24 August 1995 (1995-08-24) page 20, line 24 -page 21, line 21; figures 14,15	3-6
X	WO 96 36283 A (GEN SURGICAL INNOVATIONS INC) 21 November 1996 (1996-11-21) page 13, line 19 -page 15, line 15; figure 12	1,2,6,7
X	GB 2 275 420 A (GAUNT) 31 August 1994 (1994-08-31) abstract; figures 3,10	1

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
17 July 2000	21/07/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Moers, R

1

Form PCT/ISA/210 (second sheet) (July 1992)

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 366 478 A (CANDADAI RAMESH S ET AL) 22 November 1994 (1994-11-22) abstract; figures 1,2	1
A	US 5 741 298 A (MACLEOD CATHEL) 21 April 1998 (1998-04-21) column 8, line 61 - line 67; figure 2	9
A	WO 95 07056 A (ENCORET) 16 March 1995 (1995-03-16) cited in the application abstract; figure 9	1
A	US 5 524 644 A (CROOK BERWYN M) 11 June 1996 (1996-06-11) abstract; figures 1-6	8

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/IE 00/00033

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
US 5514133	A	07-05-1996	NONE		
WO 9522289	A	24-08-1995	IE	940150 A	04-10-1995
			IE	940613 A	04-10-1995
			IE	950055 A	07-08-1996
			AT	164303 T	15-04-1998
			AU	695770 B	20-08-1998
			AU	1717395 A	04-09-1995
			BR	9506817 A	09-09-1997
			CA	2183064 A	24-08-1995
			CN	1144471 A	05-03-1997
			CZ	9602404 A	16-04-1997
			DE	69501880 D	30-04-1998
			DE	69501880 T	23-07-1998
			EP	0744922 A	04-12-1996
			EP	0807416 A	19-11-1997
			ES	2115365 T	16-06-1998
			FI	963226 A	17-10-1996
			HU	76016 A,B	30-06-1997
			JP	9509079 T	16-09-1997
			NO	963421 A	14-10-1996
			NZ	279907 A	26-06-1998
			PL	315939 A	09-12-1996
			RU	2137453 C	20-09-1999
			US	5803921 A	08-09-1998
			ZA	9501378 A	24-10-1995
WO 9636283	A	21-11-1996	US	5634937 A	03-06-1997
			US	5964781 A	12-10-1999
GB 2275420	A	31-08-1994	NONE		
US 5366478	A	22-11-1994	NONE		
US 5741298	A	21-04-1998	US	5947922 A	07-09-1999
WO 9507056	A	16-03-1995	AT	188364 T	15-01-2000
			AU	696289 B	03-09-1998
			AU	7507494 A	27-03-1995
			CA	2171177 A	16-03-1995
			DE	69422530 D	10-02-2000
			EP	0776180 A	04-06-1997
			EP	0834279 A	08-04-1998
			EP	0888755 A	07-01-1999
			EP	0887047 A	30-12-1998
			EP	0887048 A	30-12-1998
			ES	2142404 T	16-04-2000
			JP	9502624 T	18-03-1997
US 5524644	A	11-06-1996	NONE		

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IE00/00033

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:
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1,1a,2,3	as received on	25/04/2001	with letter of	23/04/2001

Claims, No.:

1-10	as received on	25/04/2001	with letter of	23/04/2001

Drawings, sheets:

1/4-4/4	as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

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   - ☐ furnished subsequently to this Authority in computer readable form.
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- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

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6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-10
	No:	Claims	
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-10
Industrial applicability (IA)	Yes:	Claims	1-10
	No:	Claims	

2. Citations and explanations
   see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

1. Document **US 5514133 A (D1)** discloses (see Figs. 1 and 3):
A surgical access device 22 having:
body cavity engagement means 14 for insertion into the incision;
fixing means 12 for attaching the device to a patients skin;
a sleeve 16 connected between the body cavity engagement means 14 and the fixing means 12 defining an access port, whereby
the fixing means 12 is a proximal (flat) ring;
the sleeve 16 is adjustable by the positioning of the proximal ring (if the lower ring is pulled against the inside of the abdominal wall, the sleeve can be adjusted by "positioning" the proximal ring downwards);
the positioning of the proximal ring 12 contracting the sleeve and creating a seal between the incision and the sleeve;
the proximal ring 12 having an associated connector ring 40 suitable to receive additional seals or medical instruments; and
sealing means 56 operating on the sleeve to prevent leakage of gas.

Thus D1 discloses all the features of independent claim 1, except for the fact that the sleeve is contracted instead of retracted when the proximal ring is "positioned".

It would only be an obvious modification to provide the device of D1 with an alternative adjustable sleeve such as in **US-A-5524644 (D3)** which discloses a sleeve that is retracted by rolling of a proximal ring. The skilled person would incorporate this feature in the device of D1 without using any inventive skill.

2. Dependent claims 2-10 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step, the reasons being as follows:
- claim 2: see D1;
- claims 3, 4, 6 and 10: providing the device of D1 with an alternative valve at the distal side would be an obvious modification for the skilled person, as is apparently also recognised by the applicant, see description, page 7, lines 5 and 6. Such an alternative valve is known from **WO 9522289 A (D2)**, see Fig. 15;
- claim 5: foam is a material that is well known in the art for use as valve material;
- claim 7: see D1;
- claim 8: see D3, col. 3, line 18; and

- claim 9: see D1.

Re Item VIII

Certain observations on the international application

1. The term "connectable" in line 12 of claim 1 is not clear.

2. It is not clear in lines 17 and 19 of claim 1 how the "positioning of the proximal ring" would adjust the sleeve.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
P7965.WO		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/IE00/00033	20/03/2000	18/03/1999
International Patent Classification (IPC) or national classification and IPC A61B17/34		
Applicant GAYA LIMITED et al.		

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   - I ☒ Basis of the report
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   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
11/09/2000	26.07.2001
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized officer Moers, R Telephone No. +31 70 340 2375

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 : A61B 17/34 — A1

(11) International Publication Number: WO 00/54676

(43) International Publication Date: 21 September 2000 (21.09.00)

(21) International Application Number: PCT/IE00/00033

(22) International Filing Date: 20 March 2000 (20.03.00)

(30) Priority Data:
S990220 18 March 1999 (18.03.99) IE

(71) Applicant *(for all designated States except US)*: GAYA LIMITED [IE/IE]; 2–3 Sandyford Village, Sandyford, Dublin 18 (IE).

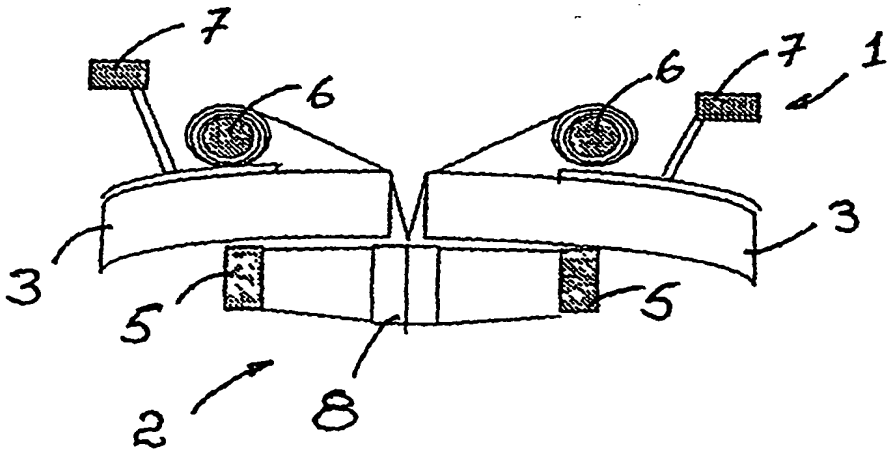
(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: CALDWELL, Martin [IE/IE]; 37 Mount Pleasant Square, Ranelagh, Dublin 6 (IE). CUMMINS, Christy [IE/IE]; 54 Knockowen Road, Tullamore, County Offaly (IE). MUNTNER, Mike [IE/IE]; 19 Doonamana Road, Dun Laoire, County Dublin (IE).

(74) Agent: MACLACHLAN & DONALDSON; 47 Merrion Square, Dublin 2 (IE).

(81) Designated States: CA, JP, US, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: A SURGICAL ACCESS DEVICE



(57) Abstract

Surgical device (1) is for use in minimally invasive surgery using an inflated body cavity (2) accessible to a surgeon through an access port defined by a sleeve (4) passing through an incision in a patient's abdominal wall (3). The device is held in position by a distal ring (5) and a proximal ring (6). The device (1) is sealed by cuff valve (8), self sealing valve (18), spring valve (28) or snap open/snap shut valve (38).

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	**ES**	Spain	**LS**	Lesotho	**SI**	Slovenia
AM	Armenia	**FI**	Finland	**LT**	Lithuania	**SK**	Slovakia
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CI	Côte d'Ivoire	**KP**	Democratic People's Republic of Korea	**NZ**	New Zealand		
CM	Cameroon			**PL**	Poland		
CN	China	**KR**	Republic of Korea	**PT**	Portugal		
CU	Cuba	**KZ**	Kazakstan	**RO**	Romania		
CZ	Czech Republic	**LC**	Saint Lucia	**RU**	Russian Federation		
DE	Germany	**LI**	Liechtenstein	**SD**	Sudan		
DK	Denmark	**LK**	Sri Lanka	**SE**	Sweden		
EE	Estonia	**LR**	Liberia	**SG**	Singapore		

A SURGICAL ACCESS DEVICE

The present invention relates to a surgical device for use in minimally invasive surgery of the type using patient pneumoperitoneum and an access port.

Minimally invasive surgery of this type is carried out having introduced gas into a patient's body cavity through an incision and sealed the incision with an access port. The access port enables laproscopic and hand or instrument assisted surgery to be performed.

A sleeve forming such a port is shown in WO-A-95/07056 entitled "Apparatus for use in surgery". The access port sleeve shown is used to create a controlled pressurized environment within the sleeve while allowing a surgeon's arm to pass through the sleeve. During surgery, gas is pumped into the patient's body cavity where the surgery is to be performed and the sleeve prevents gas escaping while allowing the surgeon to operate using minimally invasive surgery techniques. The application shows a sleeve having a flange at a distal end provided with adhesive for adhering the device to a patient's body or alternatively a mounting ring to surround the incision in a patient's body. While providing a suitable apparatus for performing such surgery the device described suffers from the principle disadvantage that in use, the sleeve protrudes upwardly from the patient and may interfere with the activities of the surgery team. Additionally, the sleeve must be sealed against the surgeon's upper forearm by clamping the device to the arm sufficiently tightly to avoid gas leak around the area of the seal. This presents the surgeon with a problem both in sealing the sleeve and in subsequent mobility.

A further problem associated with the use of sleeves of the kind described is that a phenomenon known as "tenting" may occur. "Tenting" means that when the sleeve is adhered to the patient's skin or to a surgical drape and gas is induced into the patient's abdominal cavity, there is a tendency for the sleeve to fill with gas and to pull away from the patient.

There is therefore a need for a surgical device, which will overcome the aforementioned problems.

Accordingly, there is provided a surgical device for use in minimally invasive surgery of the type using an inflated body cavity accessible to a surgeon through an access port, defined by the device, surrounding an incision in a patients body, the device having: -

body cavity engagement means for insertion into the incision to locate the device in position;

fixing means for attaching the device to a patients skin;

a sleeve connected between the body cavity engagement means and the fixing means defining an access port; and

sealing means, operating on the sleeve to prevent substantial leakage of gas from the body cavity on inflation when in an inoperative position and formed to mould a substantial portion of a surgeon's hand or surgical instrument on insertion in an operating position.

Preferably, the body cavity engagement means is provided by a distal ring formed for insertion into the incision.

In one arrangement, the distal ring has an associated cuff valve operating on the internal faces of an impermeable film, the film being located between semi rigid actuates, the actuates in turn being secured in substantially parallel manner to a distal ends of the sleeve.

Preferably the actuates are housed in opposing cuff, each cuff being formed by folding an end of a distal tube to form a pocket for reception of the actuate.

Ideally the actuates incorporate a bio-compatible medical grade foam layer to generate tension between opposing faces of the film and to operate as a cushion between the actuates and objects inserted through the cuff valve.

In an alternative arrangement, the distal ring has an associated self-sealing valve.

Preferably, the fixing means is provided by a proximal ring for engaging with a patient's skin.

In one arrangement the fixing means incorporates adjustment means for modifying the length of the sleeve. This ensures that the fixing means, distal ring and valves are brought into close contact with the abdominal wall ensuring a good seal is maintained and that the device is firmly mounted in position.

In one arrangement, the proximal ring has an associated connector ring for receiving additional seals or medical instruments.

The invention will now be described more particularly with reference to the accompanying drawings, which show, by way of example only, some embodiments of a surgical device in accordance with the invention, in which: -

Fig. 1 is a front view of a surgical device in accordance with the invention;

Fig. 2 is a section view in the direction of the arrows A-A of the surgical device of Fig. 1;

Fig. 3 is an end view of the surgical device of Figs. 1 and 2;

Fig. 4 is a side view of an alternative self sealing valve forming part of a surgical device in accordance with the invention in an inoperative position;

Fig. 5 is a side view of portion of the valve shown in Fig. 4 in an operating position;

Fig. 6 is a side view of a further alternative self sealing valve forming part of a surgical device in accordance with the invention in an inoperative position;

Fig. 7 is a side view of portion of the valve shown in Fig. 6 in an operating position;

Fig. 8 is a side view of another self sealing valve forming part of a surgical device in accordance with the invention in an inoperative position; and

Fig. 9 is a side view of portion of the valve shown in Fig. 8 in an operating position.

Referring to the drawings, and initially to Figs. 1 to 3 there is illustrated a surgical device according to the invention, indicated generally by the reference numeral 1. The surgical device 1 is formed for use in minimally invasive surgery of the type using an inflated body cavity indicated generally by the reference numeral 2. The cavity 2 is accessible to a surgeon through an access port, defined by a sleeve 4, passing through an incision in a patient's abdominal wall 3.

In more detail, the device 1 has a body cavity engagement means provided by a distal ring 5 for insertion into the incision to locate the device 1 in position. The distal ring 5 prevents the device from becoming detached from the body inadvertently and has an associated cuff valve 8 for sealing the sleeve 4 when in not in use. The device 1 is held in position on the patient's skin out side the body by a fixing means provided in this case by a proximal ring 6. The distal ring 5 and proximal ring 6 ensure that the device 1 is securely fixed in position, both rings 5,6 surround the incision and the sleeve 4 passes through the incision connecting the rings 5 and 6. The proximal ring 6 has adjustment means provided by being rotatably mounted on the skin to modify the length of the sleeve 4. This ensures that the fixing means and the distal ring 5 are brought into close contact with the abdominal wall 3 thereby, ensuring a good seal is maintained and that the device 1 is firmly mounted in position.

The proximal ring 6 may have a connector ring 7 for receiving additional seals to prevent loss of pressure from the cavity 2. The connector ring 7 may also be used for holding or guiding medical instruments into position over, through or in the incision.

In use, an incision is made in the abdominal wall 3 and the distal ring 5 and associated cuff valve 8 is passed through the incision into the cavity 2. The cuff valve 8 operates by pressing together internal faces of a flexible gas impermeable film mounted between semi-rigid actuates. The actuates are arranged substantially parallel in folded ends of a distal tube forming pockets to hold them in tension. The actuates have a bio-compatible medical grade foam along a side to cause tension between opposing faces of the film and to act as a cushion for objects inserted into the valve. The distal ring 5 is moved when in the cavity 2 so that the ring 5 surrounds the incision. The distal ring 5 thus surrounds the cuff valve 8. The proximal ring 6 can then be rotated, adjusted in height or stretched to take up the material and surplus sleeve 4 on the proximal ring 6. When the distal ring 5 is drawn up to snugly engage the internal abdominal wall 3 surrounding the incision, the proximal ring 6 is attached to the patient's skin to fix the device 1 in position. When in position, the sleeve 4 passing between the portions of the abdominal wall 3 exposed by the incision retracts the incision sides creating a lumen or bore through which an object or hand can be passed. A seal is provided by the cuff valve 8.

When a surgeon wishes to gain access to the cavity 2 a hand or instrument is passed down through the sleeve 4. The outward pressure of the retracted sleeve 4 on the abdominal wall ensures that access is not restricted. The cuff valve 8 is easily operated by the surgeon to gain access to the cavity 2 and surgery can be performed. As an object is removed, the cuff valve 8 closes down sealing the cavity 2.

It will be noted that equivalent methods of dispensing and retracting slack sleeve material following positioning of the device may be used.

Alternative embodiments of the invention are now described in which the cuff valve is replaced with a variety of self-sealing valves, however, it will be understood that the operation of these valves is not dependent on the adjustment means described above.

Referring now to Figs. 4 and 5 there is illustrated a further surgical device in accordance with the invention indicated generally by the reference numeral 20, in which parts similar to those identified with reference to Figs. 1 to 3 are identified by the same reference numerals generally. In this embodiment the cuff valve 8 has been replaced by a self-sealing valve 18. The valve 18 incorporates elasticised filaments, which are biased toward a closed position or inoperative position (see Fig. 4). When a surgeon passes a hand or instrument between the filaments which run all around the end of the sleeve 4 they are forced out of position into an operating position as shown in Fig. 5. As filaments are used they accurately mould to the surface of the inserted object preventing loss of gas from the body cavity 2. The memory resident in these filaments returns the valve 18 to the inoperative position once the object is removed to re-seal the sleeve 4.

Figs. 6 and 7 show an alternative to the cuff valve 8 described above in relation to Figs. 1 to 3. In this alternative embodiment, a spring valve 28 provides the seal to the sleeve 4. The spring valve 28 is provided by mounting a member 27 within a pocket 29 of the sleeve 4. Tension in the spring valve 28 is provided by forming the member 27 to be longer that the pocket 29. Operation of this valve is identical to that described above.

A further alternative valve is shown in Figs. 8 and 9. In this embodiment the horseshoe valve is provided as a snap open / snap shut valve 38. When positioned as described above the valve 38 is actuated by a surgeons hand or instrument to open or close the valve 38, by pivoting springed members about a pivot point 39 between an operating position as shown in Fig. 8 and an inoperative position as shown in Fig. 9. The method of biasing the members may be provided in any suitable way and the closing pressure is such as to avoid damage to any tissue, which may become trapped.

A still further arrangement, the proximal ring may be adjusted in height by means of inserting compressible foam rings between the proximal ring and the abdominal wall.

Alternatively, the sleeve may be made of an elastomer material which when the distal ring is inserted into the incision, stretches the elastomer sheet causing tension between the distal ring and the proximal ring.

It will be understood that the self-sealing valves described herein may be equally used as external proximal valves or as internal distal valves.

It will of course be understood that the invention is not limited to the specific details described herein, which are given by way of example only, and that various modifications and alterations are possible within the scope of the invention.

CLAIMS:

1. A surgical device for use in minimally invasive surgery of the type using an inflated body cavity accessible to a surgeon through an access port, defined by the device, surrounding an incision in a patients body, the device having: -

body cavity engagement means for insertion into the incision to locate the device in position;

fixing means for attaching the device to a patients skin;

a sleeve connected between the body cavity engagement means and the fixing means defining an access port; and

sealing means, operating on the sleeve to prevent substantial leakage of gas from the body cavity on inflation when in an inoperative position and formed to mould a substantial portion of a surgeon's hand or surgical instrument on insertion in an operating position.

2. A surgical device as claimed in Claim 1 in which the body cavity engagement means is provided by a distal ring formed for insertion into the incision.

3. A surgical device as claimed in Claim 2, in which the distal ring has an associated cuff valve operating on the internal faces of an impermeable film, the film being located between semi rigid actuates, the actuates in turn being secured in substantially parallel manner to a distal ends of the sleeve.

4. A surgical device as claimed in Claim 3, in which the actuates are housed in opposing cuff, each cuff being formed by folding an end of a distal tube to form a pocket for reception of the actuate.

5. A surgical device as claimed in Claim 3 or Claim 4, in which the actuates incorporate a bio-compatible medical grade foam layer to generate tension between opposing faces of the film and to operate as a cushion between the actuates and objects inserted through the cuff valve.

6. A surgical device as claimed in Claim 2, in which the distal ring has an associated self-sealing valve.

7. A surgical device as claimed in any one of the preceding claims, in which the fixing means is provided by a proximal ring for engaging with a patient's skin.

8. A surgical device as claimed in Claim 6, in which the fixing means incorporates adjustment means for modifying the length of the sleeve, so as to ensure that the fixing means, distal ring and valves may be brought into close contact with the abdominal wall ensuring a good seal is maintained and that the device is firmly mounted in position.

9. A surgical device as claimed in Claim 7, in which the proximal ring has an associated connector ring for receiving additional seals or medical instruments.

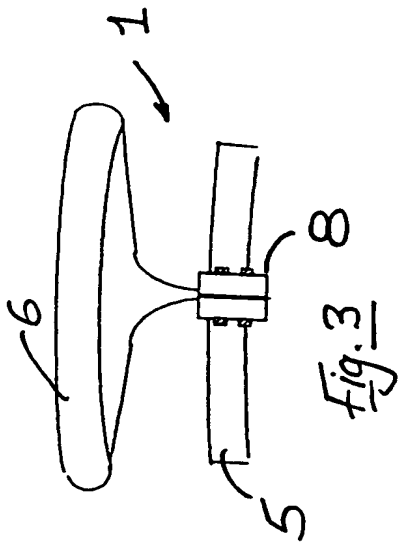

Fig.3

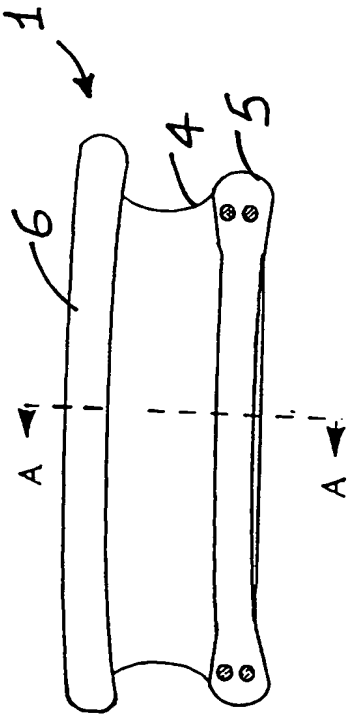

Fig.1

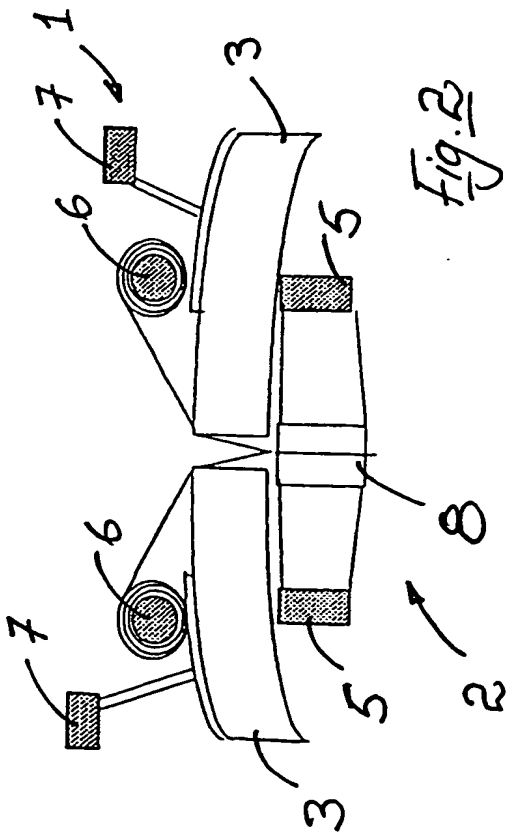

Fig.2

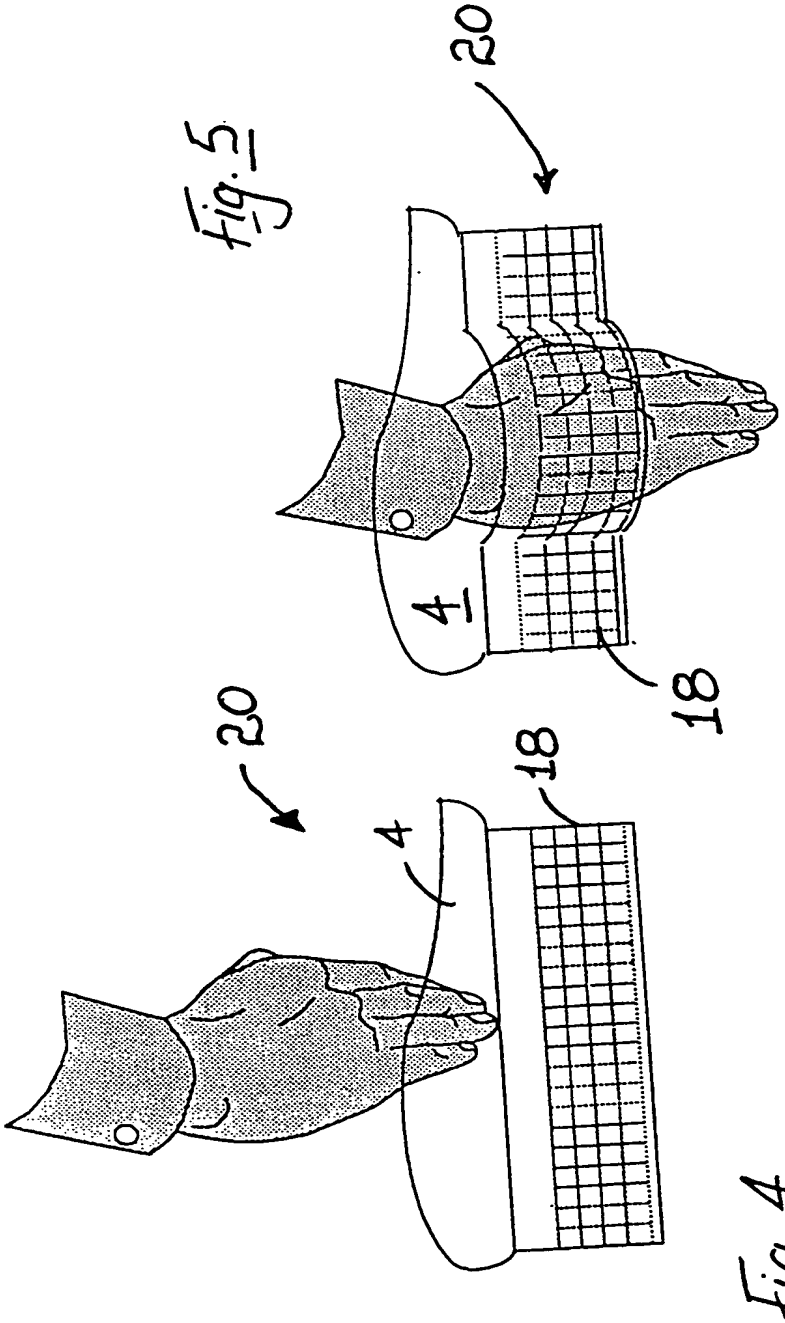

Fig. 5

Fig. 4

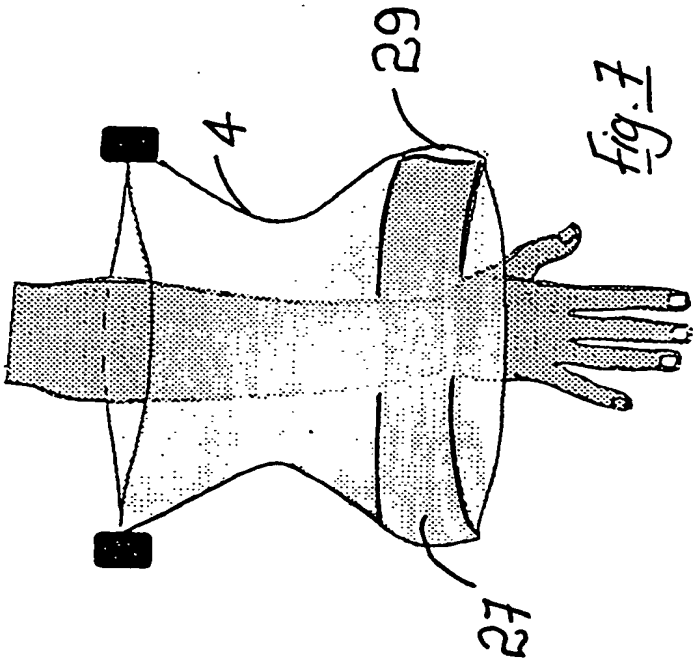

Fig. 7

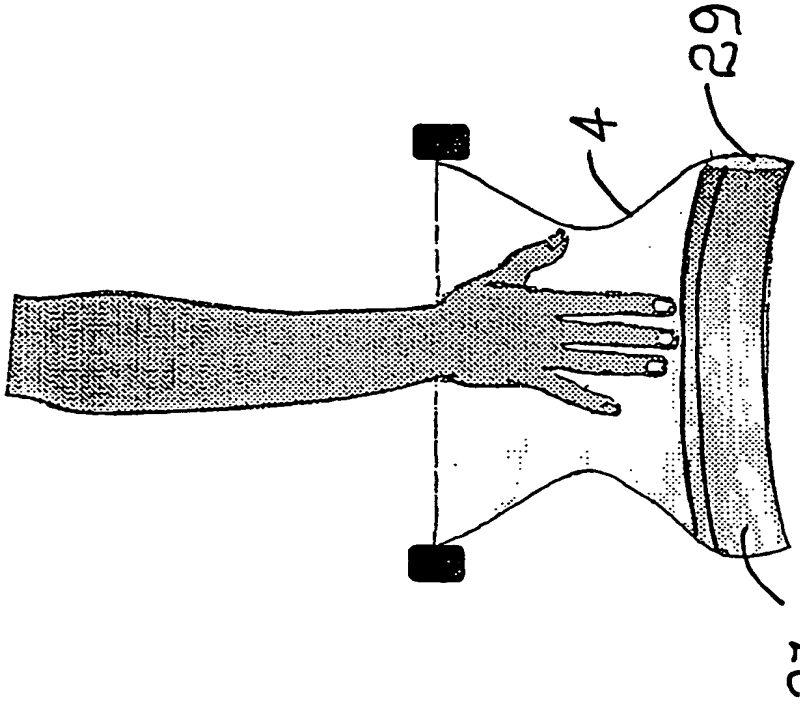

Fig. 6

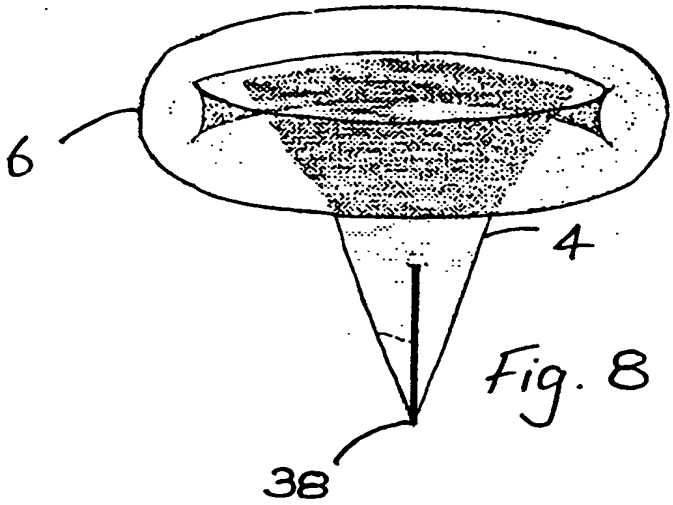

Fig. 8

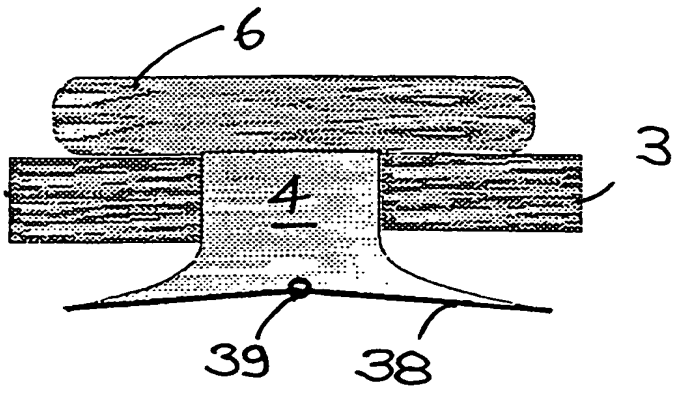

Fig. 9

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IE 00/00033

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/34

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 5 514 133 A (STEIN H DAVID ET AL) 7 May 1996 (1996-05-07) column 3, line 61 -column 5, line 14; figures 1-5	1,2,7-9 3-6
Y	WO 95 22289 A (BONADIO FRANK ;GAYA LTD (IE)) 24 August 1995 (1995-08-24) page 20, line 24 -page 21, line 21; figures 14,15	3-6
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X	GB 2 275 420 A (GAUNT) 31 August 1994 (1994-08-31) abstract; figures 3,10	1

-/—

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

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"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
17 July 2000	21/07/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Moers, R

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IE 00/00033

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
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A	US 5 741 298 A (MACLEOD CATHEL) 21 April 1998 (1998-04-21) column 8, line 61 - line 67; figure 2	9
A	WO 95 07056 A (ENCORET) 16 March 1995 (1995-03-16) cited in the application abstract; figure 9	1
A	US 5 524 644 A (CROOK BERWYN M) 11 June 1996 (1996-06-11) abstract; figures 1-6	8

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

In ...tional Application No
PCT/IE 00/00033

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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US 5524644 A	11-06-1996	NONE	

ART 34 AMDT

A SURGICAL DEVICE

Sole Spect

The present invention relates to a surgical device for use in minimally invasive surgery of the type using patient pneumoperitoneum and an access port.

Minimally invasive surgery of this type is carried out having introduced gas into a patient's body cavity through an incision and sealed the incision with an access port. The access port enables laproscopic and hand or instrument assisted surgery to be performed.

A sleeve forming such a port is shown in WO-A-95/07056 entitled "Apparatus for use in surgery". The access port sleeve shown is used to create a controlled pressurized environment within the sleeve while allowing a surgeon's arm to pass through the sleeve. During surgery, gas is pumped into the patient's body cavity where the surgery is to be performed and the sleeve prevents gas escaping while allowing the surgeon to operate using minimally invasive surgery techniques. The application shows a sleeve having a flange at a distal end provided with adhesive for adhering the device to a patient's body or alternatively a mounting ring to surround the incision in a patient's body. While providing a suitable apparatus for performing such surgery the device described suffers from the principle disadvantage that in use, the sleeve protrudes upwardly from the patient and may interfere with the activities of the surgery team. Additionally, the sleeve must be sealed against the surgeon's upper forearm by clamping the device to the arm sufficiently tightly to avoid gas leak around the area of the seal. This presents the surgeon with a problem both in sealing the sleeve and in subsequent mobility.

A further problem associated with the use of sleeves of the kind described is that a phenomenon known as "tenting" may occur. "Tenting" means that when the sleeve is adhered to the patient's skin or to a surgical drape and gas is induced into the patient's abdominal cavity, there is a tendency for the sleeve to fill with gas and to pull away from the patient.

United States Patent Specification No. US 5 514 133 discloses an endoscopic surgical apparatus for enabling a surgeon to access directly the surgical site during an endoscopic

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procedure. This apparatus includes an opening extending longitudinally through the apparatus and prior art is configured and dimensioned to receive a hand therethrough. A first plate engages against the outer surface of the abdominal wall. A second plate is spaced from the first plate and is movable between a first position and a second position wherein the second plate is in close cooperative alignment with the inner surface of the abdominal wall. An adjustment member is mounted to the second plate and actuates movement of the second plate between its first position and its second position. A first sealing member inhibits the flow of gas through said opening and is formed by a pair of overlapping seals. A flexible sleeve extends between the first and second plates and adjusts in length to accommodate various thicknesses of the abdominal wall. The sleeve also creates an access port for the passage of objects through the abdominal wall.

A surgical device for use in minimally invasive surgery of the type using an inflated body cavity accessible to a surgeon through an access port, defined by the device, surrounding an incision in a patient's body, the device having: -

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body cavity engagement means for insertion into the incision to locate the device in position;

fixing means for attaching the device to a patients skin;

a sleeve connectable between the body cavity engagement means and the fixing means; characterized in that

the fixing means is a proximal ring; and

the sleeve being adjustable by the positioning of the proximal ring;

the positioning of the proximal ring retracting the sleeve to define an access port and create a seal between the incision and sleeve;

the proximal ring having an associated connector ring for receiving additional seals or medical instruments; and

sealing means, operating on the sleeve to prevent substantial leakage of gas from the body cavity on inflation when in an inoperative position and formed to mould about a substantial portion of a surgeon's hand or surgical instrument on insertion in an operating position.

Preferably, the body cavity engagement means is provided by a distal ring formed for insertion into the incision.

In one arrangement, the distal ring has an associated cuff valve operating on the internal faces of an impermeable film, the film being located between semi rigid actuates, the actuates in turn being secured in substantially parallel manner to a distal ends of the sleeve.

ART 34 AMDT

Preferably the actuates are housed in opposing cuff, each cuff being formed by folding an end of a distal tube to form a pocket for reception of the actuate.

Ideally the actuates incorporate a bio-compatible medical grade foam layer to generate tension between opposing faces of the film and to operate as a cushion between the actuates and objects inserted through the cuff valve.

In an alternative arrangement, the distal ring has an associated self-sealing valve.

In one arrangement the fixing means incorporates adjustment means for modifying the length of the sleeve. This ensures that the fixing means, distal ring and valves are brought into close contact with the abdominal wall ensuring a good seal is maintained and that the device is firmly mounted in position.

The invention will now be described more particularly with reference to the accompanying drawings, which show, by way of example only, some embodiments of a surgical device in accordance with the invention, in which: -

Fig. 1 is a front view of a surgical device in accordance with the invention;

Fig. 2 is a section view in the direction of the arrows A-A of the surgical device of Fig. 1;

Fig. 3 is an end view of the surgical device of Figs. 1 and 2;

Fig. 4 is a side view of an alternative self sealing valve forming part of a surgical device in accordance with the invention in an inoperative position;

Fig. 5 is a side view of portion of the valve shown in Fig. 4 in an operating position;

Fig. 6 is a side view of a further alternative self sealing valve forming part of a surgical device in accordance with the invention in an inoperative position;

Fig. 7 is a side view of portion of the valve shown in Fig. 6 in an operating position;

Fig. 8 is a side view of another self sealing valve forming part of a surgical device in accordance with the invention in an inoperative position; and

Fig. 9 is a side view of portion of the valve shown in Fig. 8 in an operating position.

Referring to the drawings, and initially to Figs. 1 to 3 there is illustrated a surgical device according to the invention, indicated generally by the reference numeral 1. The surgical device 1 is formed for use in minimally invasive surgery of the type using an inflated body cavity indicated generally by the reference numeral 2. The cavity 2 is accessible to a surgeon through an access port, defined by a sleeve 4, passing through an incision in a patient's abdominal wall 3.

In more detail, the device 1 has a body cavity engagement means provided by a distal ring 5 for insertion into the incision to locate the device 1 in position. The distal ring 5 prevents the device from becoming detached from the body inadvertently and has an associated cuff valve 8 for sealing the sleeve 4 when in not in use. The device 1 is held in position on the patient's skin out side the body by a fixing means provided in this case by a proximal ring 6. The distal ring 5 and proximal ring 6 ensure that the device 1 is securely fixed in position, both rings 5,6 surround the incision and the sleeve 4 passes through the incision connecting the rings 5 and 6. The proximal ring 6 has adjustment means provided by being rotatably mounted on the skin to modify the length of the sleeve 4. This ensures that the fixing means and the distal ring 5 are brought into close contact with the abdominal wall 3 thereby, ensuring a good seal is maintained and that the device 1 is firmly mounted in position.

The proximal ring 6 may have a connector ring 7 for receiving additional seals to prevent loss of pressure from the cavity 2. The connector ring 7 may also be used for holding or guiding medical instruments into position over, through or in the incision.

In use, an incision is made in the abdominal wall 3 and the distal ring 5 and associated cuff valve 8 is passed through the incision into the cavity 2. The cuff valve 8 operates by pressing together internal faces of a flexible gas impermeable film mounted between semi-rigid actuates. The actuates are arranged substantially parallel in folded ends of a distal tube forming pockets to hold them in tension. The actuates have a bio-compatible medical grade foam along a side to cause tension between opposing faces of the film and to act as a cushion for objects inserted into the valve. The distal ring 5 is moved when in the cavity 2 so that the ring 5 surrounds the incision. The distal ring 5 thus surrounds the cuff valve 8. The proximal ring 6 can then be rotated, adjusted in height or stretched to take up the material and surplus sleeve 4 on the proximal ring 6. When the distal ring 5 is drawn up to snugly engage the internal abdominal wall 3 surrounding the incision, the proximal ring 6 is attached to the patient's skin to fix the device 1 in position. When in position, the sleeve 4 passing between the portions of the abdominal wall 3 exposed by the incision retracts the incision sides creating a lumen or bore through which an object or hand can be passed. A seal is provided by the cuff valve 8.

When a surgeon wishes to gain access to the cavity 2 a hand or instrument is passed down through the sleeve 4. The outward pressure of the retracted sleeve 4 on the abdominal wall ensures that access is not restricted. The cuff valve 8 is easily operated by the surgeon to gain access to the cavity 2 and surgery can be performed. As an object is removed, the cuff valve 8 closes down sealing the cavity 2.

It will be noted that equivalent methods of dispensing and retracting slack sleeve material following positioning of the device may be used.

Alternative embodiments of the invention are now described in which the cuff valve is replaced with a variety of self-sealing valves, however, it will be understood that the operation of these valves is not dependent on the adjustment means described above.

Referring now to Figs. 4 and 5 there is illustrated a further surgical device in accordance with the invention indicated generally by the reference numeral 20, in which parts similar to those identified with reference to Figs. 1 to 3 are identified by the same reference numerals generally. In this embodiment the cuff valve 8 has been replaced by a self-sealing valve 18. The valve 18 incorporates elasticised filaments, which are biased toward a closed position or inoperative position (see Fig. 4). When a surgeon passes a hand or instrument between the filaments which run all around the end of the sleeve 4 they are forced out of position into an operating position as shown in Fig. 5. As filaments are used they accurately mould to the surface of the inserted object preventing loss of gas from the body cavity 2. The memory resident in these filaments returns the valve 18 to the inoperative position once the object is removed to re-seal the sleeve 4.

Figs. 6 and 7 show an alternative to the cuff valve 8 described above in relation to Figs. 1 to 3. In this alternative embodiment, a spring valve 28 provides the seal to the sleeve 4. The spring valve 28 is provided by mounting a member 27 within a pocket 29 of the sleeve 4. Tension in the spring valve 28 is provided by forming the member 27 to be longer that the pocket 29. Operation of this valve is identical to that described above.

A further alternative valve is shown in Figs. 8 and 9. In this embodiment the horseshoe valve is provided as a snap open / snap shut valve 38. When positioned as described above the valve 38 is actuated by a surgeons hand or instrument to open or close the valve 38, by pivoting springed members about a pivot point 39 between an operating position as shown in Fig. 8 and an inoperative position as shown in Fig. 9. The method of biasing the members may be provided in any suitable way and the closing pressure is such as to avoid damage to any tissue, which may become trapped.

A still further arrangement, the proximal ring may be adjusted in height by means of inserting compressible foam rings between the proximal ring and the abdominal wall.

Alternatively, the sleeve may be made of an elastomer material which when the distal ring is inserted into the incision, stretches the elastomer sheet causing tension between the distal ring and the proximal ring.

It will be understood that the self-sealing valves described herein may be equally used as external proximal valves or as internal distal valves.

It will of course be understood that the invention is not limited to the specific details described herein, which are given by way of example only, and that various modifications and alterations are possible within the scope of the invention.

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CLAIMS:

1. A surgical device (1) for use in minimally invasive surgery of the type using an inflated body cavity (2) accessible to a surgeon through an access port, defined by the device (1), surrounding an incision in a patient's body, the device (1) having: -

body cavity engagement means (5) for insertion into the incision to locate the device (1) in position;

fixing means (6) for attaching the device to a patients skin;

a sleeve (4) connectable between the body cavity engagement means and the fixing means; characterized in that

the fixing means is a proximal ring (6); and

the sleeve is adjustable by the positioning of the proximal ring;

the positioning of the proximal ring retracting the sleeve to define an access port and create a seal between the incision and sleeve;

the proximal ring (6) having an associated connector ring (7) for receiving additional seals or medical instruments; and

sealing means, operating on the sleeve to prevent substantial leakage of gas from the body cavity on inflation when in an inoperative position and formed to mould about a substantial portion of a surgeon's hand or surgical instrument on insertion in an operating position.

2. A surgical device as claimed in Claim 1 in which the body cavity engagement means (5) is provided by a distal ring (5) formed for insertion into the incision.

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3. A surgical device as claimed in Claim 2, in which the distal ring has an associated cuff valve (8) operating on the internal faces of an impermeable film, the film being located between semi rigid actuates, the actuates in turn being secured in substantially parallel manner to a distal end of the sleeve.

4. A surgical device as claimed in Claim 3, in which the actuates are housed in opposing cuffs, each cuff being formed by folding an end of a distal tube to form a pocket for reception of the actuate.

5. A surgical device as claimed in Claim 3 or Claim 4, in which the actuates incorporate a bio-compatible medical grade foam layer to generate tension between opposing faces of the film and to operate as a cushion between the actuates and objects inserted through the cuff valve (8).

6. A surgical device as claimed in Claim 2, in which the distal ring (5) has an associated self-sealing valve (18).

7. A surgical device as claimed in Claim 6, in which the fixing means (6) incorporates adjustment means for modifying the length of the sleeve, so as to ensure that the fixing means (6), distal ring (5) and valves (8,18,28,38) may be brought into close contact with the abdominal wall ensuring a good seal is maintained and that the device (1) is firmly mounted in position.

8. A surgical device as claimed in any one of the preceding claims in which the sleeve is made of an elastomer material, whereby insertion of the distal ring into an incision stretches the elastomer material causing tension between the distal ring and proximal ring.

9. A surgical device as claimed in Claim 6, in which the self sealing valve (18,28,38) is an external proximal valve.

10. A surgical device as claimed in Claim 6 or Claim 9 in which the self-sealing valve (18,28,38) is an internal distal valve.